

REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks with respect to the anticipation rejection, and a potential obviousness rejection.

Status of Claims

Claims 1-10 are pending.

Claim Rejections-35 USC §102

Claims 1-10 were solely rejected under 35 U.S.C. § 102(b) as anticipated by KATO (US 5,932,259). This rejection is respectfully traversed for the reasons below.

The position of Official Action was that the composition of KATO comprising 40%wt or more lactoperoxidase (hereafter LPO) is identical to the claims.

However, KATO fails to disclose at least two of the claimed features of the present invention:

I. LPO having a purity of at least 91%.

While KATO may disclose that the protein fraction contains 40 wt% or more of LPO, KATO also discloses that this protein fraction additionally contains 40 wt% or more of lactoferrin. See, e.g., column 4, lines 63-67. Indeed, KATO confirms that the protein fraction comprises two major proteins, e.g., lactoferrin and LPO(column 3, lines 9-16).

Thus, as there is no mention of purification of LPO, i.e., separation from lactoferrin, KATO fails to inherently teach at least 91% purity of LPO.

II. LPO and/or product with an osteogenesis promoting effect.

KATO discloses a basic protein derived from milk that has bone reinforcing effects. This basic protein comprises various components in addition LPO.

KATO fails to disclose, however, that LPO, or a digestion product thereof, has an osteogenesis promoting effect. Indeed, KATO never identifies any particular component as necessary for the functional activity.

At best, KATO suggests that the bone reinforcing effects are achieved by a basic protein fraction which includes two major proteins, lactoferrin and LPO, each of which must be at least 40wt% or more.

Thus, KATO fails to inherently teach that LPO itself and/or a digestive product thereof having an osteogenesis promoting effect.

Therefore, for at least the two reasons above, KATO does not anticipate the claimed invention, and withdrawal of the rejection is respectfully requested.

KATO would also fail to render obvious the claimed invention.

That is, it would have been unobvious to one of ordinary skill in the art in light of the teachings of KATO to obtain a minimum effect in osteogenesis with compositions comprising highly purified LPO, i.e., at least 91% purity, when delivered in lower doses than those comprising less purified LPO.

As discussed above, KATO requires two major proteins in a protein fraction, e.g., lactoferrin and LPO, each of which must be at least 40wt% or more, and purification of LPO to at least 91% would be contrary to this requirement.

Moreover, KATO discloses administration of 0.5 g/day is necessary using 46.5% LPO; while in the present invention, administration of only 10 mg/day is sufficient using 91% LPO. When the amount of LPO which brings about the osteogenesis promotion is calculated, 0.2325g/day (232 mg/day) of LPO is necessary from the composition of KATO, while 9.1 mg/day of LPO in the present invention.

Thus, KATO fails to disclose or suggest the efficacy in osteogenesis with compositions comprising highly purified LPO, as evidenced by the fact that the LPO of the present invention brings about the same effect with the amount of 1/20 of the amount of LPO required by KATO.

In order to prove the unexpected result of the present invention applicants investigated the osteoblast differentiation promoting effecting of the LPO obtained by the method of Example 1 of the present invention and of milk-derived basic protein obtained by a method described in KATO (content of LPO of 46.5%) using the same method as described in Test Example 1 of the present specification. The result is shown below along with the result in Test Example 1. It is clear that the osteoblast differentiation promoting effect of the basic protein of KATO, which additionally includes lactoferrin, is inferior to that of the composition of the LPO having a purity of 91% of the claimed invention.

	LPO content	Final concentration of LPO	Amount of collagen
Control	0	-	100±6
KATO	46.5%	100 µg/ml	134±1
CLAIMED INVENTION	91%	100 µg/ml	203±2
TEST EXAMPLE 1	91%	10 µg/ml	191±4
TEST EXAMPLE 1	91%	100 µg/ml	188±6

In the present invention, a similar effect is obtained at the level of 10µg/ml as at the level of 100µg/ml, which indicates that the present invention shows unexpected results compared to KATO.

KATO discloses that a composition of LPO (46.5%) and lactoferrin has an osteoblast differentiation promoting effect, but it was not obvious over KATO that a highly purified LPO which does not contain lactoferrin has a much improved osteoblast differentiation promoting effect.

Conclusion

In view the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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